Code: AP.PRE.REQ

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE nder the Papenvork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. Docket Number (Optional) PRE-APPEAL BRIEF REQUEST FOR REVIEW Application Number I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail 09/761,538 d23/200/ in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450° [37 CFR 1.8(a)] First Named Inventor Examiner Typed or printed Lundgren, Teffley S. 1639 name Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request. This request is being filed with a notice of appeal. The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided. I am the applicant/inventor. assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96) (508) 856- 7900 Telephone number attorney or agent of record. Registration number 09-24-06 attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _ NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.

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Application No.

09/767,538

Applicant:

Wang et al.

Serial No.:

09/767,538

Filed:

January 23, 2001

For:

ARRAYS FOR BRINGING TWO OR MORE REAGENTS IN

CONTACT WITH ONE OR MORE BIOLOGICAL TARGETS AND

METHODS FOR MAKING AND USING THE ARRAYS

Examiner

Lundgren, Jeffrey S.

Group:

1639

Mail Stop AF

Commissioner of Patents

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Introductory Remark

This document is in support of the Pre-Appeal Brief Request for Review being filed. The Office Action dated May 24, 2006 in the subject application rejected the instant claims. The Applicant appreciates the Examiner's examination of the application but believe that the rejections have been previously overcome.

During the course of the examination, four different Examiners (Maurie G. Baker, Bennett Celsa, Padmashri Ponnaluri, and Jeffrey S. Lundgren) have examined the application. The Applicant believes that the frequent change of Examiners may have caused extra burdens and delays to the application. The Applicant respectfully appeals the Examiner's current rejections and argues that similar rejections have been raised in the previous Office Actions and they have been overcome in the responses to the previous Office Action. Applicant therefore respectfully requests consideration and allowance of the application.

Remark 1. The Objections in the Office Action dated May 24, 2006 was raised previous in Office Actions dated April 23, 2004 and in Office Action dated May 03,

2005 (although Claim 37 was modified, the current claim is narrower than the previous claim).

In the Office Action dated May 24, 2006 Claims 37-39, 43-46 and 53 are rejected under 35USC 102(e) as being anticipated by Moynihan et al., US Pat. No. 6,365,349 B1.

"Claim is directed to a method of bringing two or more reagents into contact with one or more biological targets, comprising an array of reagents contacting a group of biological targets on cell growth support, wherein the reagents locations are addressed.

Moynihan teaches an improved pipette dispenser for use in biological assays in array format. Moynihan teaches that her invention is relevant to the combinatorial arts for the testing of many samples (i.e., two or more reagents)...

Moynihan discloses a well-known apparatus in the art for dispensing the reagents to the array for delivery the two or more reagents...

Moynihan, col. 3, lines 1-13 (emphasis added). The pipette comprise "barriers" as claimed by Applicants, as Applicants' claims are open to the physical geometries of the barriers."

However, the same reason for this rejection was used in the rejection in the Office Action dated April 23, 2004.

In rejecting Claim 37, the Office Action dated April 23, 2004 states that "Claims 37-39, 43-45, and 47-48 were rejected under 35 U.S.C. §102(e) as anticipated by Chin et al. (U.S. Patent No. 6,197,599, issued 3/01, filed 7/98)... Chin et al. teach both a method and apparatus for making micro arrays comprising "'two or more reagents' (e.g. 2 or more polynucleotides or polypeptides) and 'one or more barriers... wherein each portion is maintained at predefined positions... portions is adapted to be brought into contact with one or more predefined biological targets' in which the 'barrier' comprises a 'solid support' (e.g. uncoated or glass coated with a polymer i.e. polylysine and grids e.g. addresses)"

Although the references used are different (the current rejection was over Moynihan while the rejection in the Office Action dated April 23, 2004 was over Chin et al.), the reasons are identical: the reference teaches the use of reagent arrays.

As argued previously, although both references (Moynihan and Chin) teaches the method of providing an array of 2 or more reagents, the reference does not teach the method of Claim 37, namely, the step of providing an array and providing cells on a separate cell growth support; the step of applying one or more conditions to one or more of said reagent portions to facilitate said transfer of some or all of each specific reagent portion to said specific reagent portion's corresponding biological target, whereby some or all of each specific reagent portion dissociates from said barriers and is transferred to said specific reagent portion's corresponding biological target immobilized on said cell growth support. The references did not teach the step of separating said cell growth support from said array (as in Claim 53) either.

The reason for rejecting Claim 37 was also described in the Office Action dated May 03, 2005. Specifically, Claims 37, 43-46 and 53-55 are rejected under 35 USC 102 as being anticipated by Palsson US Pat. 5,811,274.

In rejecting the instant claims, The Office Action dated May 03, 2005 states that "Palsson teaches a method of contacting 2 or more reagents with 1 or more biological targets comprising: a. providing an array or 2 or more reagents (e.g. "particles"; see col. 4 and patent claims) on a coated (e.g. polylysine) or uncoated "support" (e.g. cell growth support: see col. 5, especially lines 38- including membranes i.e. porous)...
b. providing 1 or more biological targets 9e.g. eukaryotic cells: see col. 5) for contacting the reagent array in which the "biological targets' can be "localized" for contacting and/or immobilized (e.g. attached) to a support (e.g. see col. 3, especially lines 30-40); c and d.. applying 1 or more "conditions" to promote contact, dissociation and transfer (e.g. transfection) (e.g. see bottom of col. 7-col. 8) of the particle DNA into the cell(s) into the corresponding target cell(s). See also example and patent claims".

In both previous cases, the rejections were withdrawn.

Remark 2. Claims 37, 43-46, 49 and 53-55 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Balch, US Pat. 6,083,763 in view of Moynihan et al., US Pat. No. 6,365,349 B1.

"Balch teaches a method and apparatus for analyzing molecular structures within a sample substance using an array having a plurality of test sites upon which the sample substance is applied...

One of ordinary skill in the art would have had a reasonable expectation of success in arriving at the invention as claimed because each of Balch and Moynihan teach laboratory based assays via the use of automated, array-based fluid deposition apparatus..."

Similar Rejections were raised in previous Office Action dated May 03, 2005. Claims 37, 43-46, 49 and 53-55 are rejected as being unpatentable over Palsson US Pat. 5,811,274 in view of Sabatini US Pat. No. 6,544,790.

"The Palsson reference teaching differs from the presently claimed invention by failing to teach applying electric impulses (e.g. electroporation) to the reagent as one of the conditions (e.g. present claims 49 and 56)".

"Electroporation is a conventional means of promoting transfection as illustrated by the Sabatini reference (e.g. see col. 1, especially lines 30-40)".

"Accordingly, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to modify the Palsson reference (see Palson at col. 8: which incorporated "standard" transfection conditions) in order to further promote transfection efficiency".

Although both Balch and Moynihan teach the method and apparatus using array format and Moynihan teaches growth of cells in 96-well microtiter plates, neither reference suggest the use of arrays of regents with cells growing on a support. Balch teaches the method of making arrays, wherein electric pulses may be used to dispense the reagents (col. 11, lines 33-54). However, it did not suggest to transfect the reagents from the arrays into cells. Moynihan teaches cells culture but did not teach at all to use the method of making and using arrays for transfecting cells. Therefore, neither method

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suggest the combination of using reagent arrays and cells to transfect the reagents into cells in a positional addressable manner, as in the method of Claim 37.

Even a person in the art applies Balch's apparatus to the cell-assays as taught by Moynihan, that will not result in the method of Claim 37 because the dispense of reagent from arrays in Balch's apparatus into cell medium will not result in the transfection of the reagent into cells in a position-addressable manner (as the method of Claim 37).

Respectfully submitted,

Yingjian Wang

September 24, 2006